

REMARKS

1. Applicant has amended the specification to include a priority claim, inadvertently omitted from the application at the time of filing. Applicant respectfully points out that the priority claim was timely made in the application data sheet, and that the priority claim was acknowledged, albeit incorrectly, in the filing receipt. Accordingly, a petition to accept an unintentionally delayed priority claim is unnecessary.

2. Claims 1 – 48 stand rejected under 35 USC § 112, second paragraph as being indefinite for failing to distinctly claim and particularly point out the subject matter of the invention. Claim 1 has been amended to describe the arm position as “comfortable.” “Comfortable” is a self-defining term, the meaning of which is readily discerned by the practitioner having an ordinary level of skill. Claim 1 has been further amended to eliminate the offending term “minimize,” substituting the feature “limit...to distinct registration points.” Support for the amendment is found in the Figures and in the specification at least at page 9, lines 27 – 30. Claims 11 and 30 have been similarly amended. Thus, the rejection of Claims 1 – 48 under 35 USC § 112, second paragraph is deemed overcome.

3. Claims 1 – 4, 7 - 8, 11 – 18, 21 and 23 – 27 stand rejected under 35 USC 102(e) as being anticipated by U.S. Patent No. 6,026,131 (“Kexin”).

Regarding Claim 1: To distinguish the invention from the cited reference more thoroughly, Applicant has amended Claim 1 to specify that contact of the arm bearing the tissue measurement site with the interface module is limited to distinct registration points. The invention recognizes that skin temperature transients resulting from contact of the body part with environmental surfaces account for a significant amount of interference in the spectral measurement. Thus, an apparatus is provided that limits contact of the arm bearing the measurement site to distinct registration points established by the elbow, wrist and hand rests.

In stark contrast, Kexin provides an apparatus, shown in Figure 11, in which substantially the entire surface of the forearm is in direct contact with the placement apparatus. Furthermore, as shown in Figure 4, substantially the entire finger bearing the measurement site, excepting the measurement site itself, is in close contact with the set probe. Thus, Kexin fails completely to contemplate the adverse effect of skin temperature transients resulting from contact with environmental surfaces on the spectral measurement or to provide any means of controlling such transients.

- 10 The Examiner relies on Figure 11 of Kexin as teaching a "base defining an aperture." Applicant respectfully disagrees. Figure 11 of Kexin shows a support 60 bearing elliptical markings of some sort on its upper surface. There is absolutely no description of the markings in the specification; thus, the Examiner's presumption that the markings represent an "aperture that communicates" from the bottom surface to the top
15 surface of the support is completely unfounded.

The Examiner relies on Kexin's adjuster 62 (Figure 11) as teaching an elbow support. While the adjuster does support the elbow, there is no teaching in Kexin that the supporter 62 is "replaceably attached" to the supporter 60.

- 20 The Examiner relies on Kexin's presser member 64 (Figure 11) as teaching a wrist support. Applicant respectfully disagrees. The practitioner of ordinary skill would readily understand the wrist support of Claim 1 to be a rest. In stark contrast, Kexin's presser member is an inflatable sleeve that restrains the arm, preventing movement. A
25 wrist restraint is not a wrist support. Nor would the practitioner of ordinary skill consider them to be equivalent. Furthermore, there is no teaching in Kexin that the presser member is "replaceably attached to the supporter 60."

- 30 There is no basis for the Examiner's finding that the set probe 10 is attached to the supporter 60. While Figures 7 and 8 of Kexin show the set probe 10 attached to structure 16, structure 16 functions to couple the set probe to the measurement probe.

The Examiner's presumption that the structure 16 is attached to the supporter 60 is completely unsupported by the reference. Furthermore, the Examiner appears to have found that the set probe 10 is attached to the supporter 60 because the set probe 10 is positioned proximally to the supporter in Figure 11. However, Figure 11 provides no
5 indicia that the two components are attached, and the accompanying description provides no support for such a finding.

In view of the above, the rejection of Claim 1 under 35 USC § 102 (e) would have been improper, even without amendment. Having been amended, Claim 1 clearly
10 describes subject matter patentably distinct from that of Kexin. Thus, Claim 1 and all Claims depending therefrom are allowable over Kexin.

Regarding Claim 11: Claim 11 has been amended to describe the supports as limiting contact of a member bearing the tissue measurement site with the interface module to
15 distinct registration points. As described above, in Kexin, substantially the entire limb and finger bearing the measurement site are in contact with the supporter, the presser member, and the set probe. As such, the rejection of Claim 11 under 35 USC § 102(e) is deemed to be overcome. Therefore, Claim 11 and all Claims depending therefrom are deemed to be allowable.

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3. Claims 6 and 22 stand rejected under 35 USC 103(a) as being unpatentable over Kexin in view of U.S. Patent No. 3,785,196 ("Smith"). While the amendments to Claims 1 and 11 render the current rejection moot, Applicant notes that Smith is directed to an apparatus for testing shear stability of lubricants, an art completely
25 nonanalogous to that of the current invention: noninvasive spectral measurements conducted on living subjects. Accordingly, one of ordinary skill in the field of the invention would never be lead to combine the teachings of Kexin and Smith to derive the Claimed invention. Thus, were it not rendered moot by the amendments of Claims 1 and 11, the current rejection would be improper.

4. Claims 5 and 19 – 20 stand rejected under 35 USC 103(a) as being unpatentable over Kexin in view of U.S. Patent No. 6,088,605 ("Griffith") and further in view of U.S. Patent No. 5,195,985 ("Hall"). While the amendments to Claims 1 and 11 render the current rejection moot, Applicant notes that Griffith teaches away from the Claimed Invention. As discussed in the body of the Application, Griffith makes no attempt to physically limit or control interference resulting from placement errors, pressure variations and skin temperature transients. Rather, Griffith merely attempts to average the error out by making repeated measurements. Furthermore, Hall is concerned with a problem completely unrelated to that addressed by the current invention. Hall merely provides finger depressions on the side of a phlebotomy apparatus that allow the operator to grip it more comfortably, thus increasing the possibility that the phlebotomy will be successful. As such, one having an ordinary level of skill would never be lead to combine the teachings of Kexin, Griffiths and Hall to derive the Claimed invention. Thus, were it not rendered moot by the amendments of Claims 1 and 11, the current rejection would be improper.

5. Claims 9 and 28 stand rejected under 35 USC 103(a) as being unpatentable over Kexin. The current rejection is rendered moot by the amendments to Claims 1 and 11.

6. Claims 10 and 29 stand rejected under 35 USC 103(a) as being unpatentable over Kexin in view of U.S. Patent No. 5,368,025 ("Young"). The current rejection is rendered moot by the amendments to Claims 1 and 11.

7. Claims 30 – 39 and 44 – 48 stand rejected under 35 USC 103(a) as being unpatentable over Kexin in view of U.S. Patent No. 6,039,697 ("Wilke"). Applicant respectfully disagrees. While Wilke recognizes that it is important to isolate the sample from the energy source in order to avoid heating the sample, the invention recognizes that temperature transients caused by contact of the member bearing the sample site with the interface module, not the energy source, are a significant source of error. An energy source is not a subject interface module. Claim 30, as amended, specifically

describes a step of "limiting surface temperature transients at said tissue measurement site, wherein said temperature transients are caused by contact of said member with a subject interface module." Wilke fails to contemplate that skin temperature transients resulting from contact of the member bearing the sample site with an interface module are significant sources of error, nor does Wilke provide any means for limiting or compensating such error. Because the references, either separately or in combination, fail to teach or suggest all features of Claim 30, the rejection under 35 USC 103(a) is improper. Accordingly, Claim 30, and all Claims depending therefrom are deemed to be allowable.

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8. Claims 1 and 11 have been amended to describe the invention as an "interface module" for "limiting sampling variations..." Support for the amendment is found in the specification at page 6, line 2 to line 8.

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9. Claim 30 has been amended to describe the invention as a "method of limiting sampling variations..." Support for the amendment is found as above

10. Claims 41 and 43 have been amended to harmonize them with their parent Claim.

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11. New Claims 49 - 56 have been added to the application. Applicant avers that no new matter was added by way of the new Claims.

CONCLUSION

In view of the foregoing, the application is deemed to be in allowable condition.

- 5 Therefore, the Examiner is earnestly requested to withdraw all rejections and allow the application to pass to issuance as a U.S. Patent. Should the Examiner have any questions concerning the Application, he is urged to contact Applicant's attorney at the telephone number given below.

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Respectfully Submitted,



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AMENDMENTS (MARKED UP COPY)

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At page 1, please insert the following immediately following the title:

CROSS REFERENCE TO RELATED APPLICATIONS

10 This application claims benefit of U.S. Provisional Patent Application Ser. No. 60/235,424, filed on September 26, 2000, and is a continuation-in-part-application of U.S. Patent Application Ser. No. 09/563,782 filed on May 2, 2000 and is also a continuation-in-part application of U.S. Patent Application Ser. No. 09/631,440, filed on August 2, 2000.

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In the claims:

1. (Amended) An [minimal contact] interface module for [minimizing] limiting
20 [spectral interference] sample variation during *in-situ* spectral sampling at a tissue measurement site on an arm of a live subject, comprising:
a base having a top surface, a bottom surface and opposing ends, said base defining an aperture that communicates from said bottom surface to said top surface;
an elbow support, said elbow support replaceably attached to said top surface
25 at a first of said opposing ends;
a wrist support, said wrist support replaceably attached to said top surface toward a second of said opposing ends; and
a hand support, said hand support slideably attached to said base at said second of said opposing ends and protruding from said opposing end;
30 wherein said arm is received by said interface module so that said arm is supported in a comfortable [natural] position and reproducibly positioned in relation to a fiber optic probe;
wherein said supports limit [minimize] contact of said [tissue measurement site] arm with said interface module to distinct registration points; and
35 wherein said interface module is customizable to individual subjects.

11. (Amended) An interface module for [minimizing] limiting [spectral interference] sample variation during *in-situ* spectral sampling at a tissue measurement site, comprising:

5 a base having two opposing surfaces and two opposing ends;
a plurality of support elements mounted on said base, wherein said support elements are adapted to receive a member bearing said tissue measurement site so that said tissue measurement site is reproducibly positioned and supported in relation to an optical coupling means, wherein said supports limit contact of said [tissue measurement site] member with said interface module to distinct registration points;
10 and

wherein said interface module is adjustable to individual subjects.

30. (Amended) A method of [minimizing] limiting [spectral interference] sample variation during *in-situ* spectral sampling at a tissue measurement site comprising the steps of:

15 limiting [minimizing] variations in placement of a tissue measurement site in relation to an optical coupling means;

20 limiting [minimizing] variations in pressure applied by an optical coupling means to said tissue measurement site; and

limiting [minimizing] surface temperature transients at said tissue measurement site, wherein said temperature transients are caused by contact of said member with a subject interface module;

25 wherein signal-to-noise ratio is optimized to facilitate net analyte signal detection.

41. (Amended) The method [interface module] of Claim 38, wherein said elbow support is provided in a plurality of shapes and sizes, according to diameter of said elbow.

30 43. (Amended) The method [interface module] of Claim 42, wherein said means for adjusting elbow height comprises at least one shim, wherein said shim is placed beneath said elbow support, and wherein said shim is provided in a plurality of thicknesses.

Please add new Claims 49 – 56 as follow:

49. An interface module for limiting sample variation during *in-situ* spectral sampling at a tissue measurement site, comprising:

_____ one or more support elements mounted on said base, wherein said one or more support elements are adapted to receive a member bearing said tissue measurement site so that said tissue measurement site is reproducibly positioned and supported in relation to an optical coupling means, wherein said one or more support elements limit contact of said member with said interface module to distinct registration points.

50. The interface module of Claim 49, further comprising a base, wherein said one or more support elements are mounted on said base.

51. A method of limiting sample variation during *in-situ* spectral sampling at a tissue measurement site comprising the steps of:

_____ limiting variations in placement of a tissue measurement site in relation to an optical coupling means; and

_____ limiting variations in pressure applied by an optical coupling means to said tissue measurement site by limiting contact of a member bearing said tissue measurement site to distinct registration points.

52. The method of Claim 51, further comprising a step of:

_____ limiting surface temperature transients at said tissue measurement site.

53. The method of Claim 51, wherein signal-to-noise ratio is optimized to facilitate net analyte signal detection.

54. A method of limiting sample variation during *in-situ* spectral sampling at a tissue measurement site comprising the steps of:

_____ limiting variations in placement of a tissue measurement site in relation to an optical coupling means; and

_____ limiting surface temperature transients at said tissue measurement site, wherein said temperature transients are caused by contact of a member bearing said tissue measurement site with a subject interface module.

55. The method of Claim 54, further comprising a step of:
limiting variations in pressure applied by an optical coupling means to said
tissue measurement site.

5 56. The method of Claim 54, wherein signal-to-noise ratio is optimized to facilitate
net analyte signal detection.

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